IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 2 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION OPINION TESTIMONY OF KONSTANTIN WALMSLEY, M.D.

Plaintiffs listed have identified Konstantin Walmsley, M.D. as their general-causation expert. Although Dr. Walmsley's two general-causation opinions are separately set forth in each of the five Rule 26 reports for the plaintiffs listed in Exhibit A, the opinions are essentially identical, often verbatim, and are generally confined to the adequacy of the Instructions for Use (IFU) for the TVT, TVT-O, and TVT-Secur products. If permitted, he will testify that IFUs did not reference certain conditions and therefore were "not sufficient to enable informed consent from the patient." Exs. B (Bailey), C (Lindberg), D (Manor), E (Martin), F (Pridmore), Walmsley Reports, Gen. Op. 1.[1] Second, he claims that Plaintiffs were unable to receive "proper

[1] Dr. Walmsley's Rule 26 reports contain no page numbers, but the first two opinions in each report are his general opinions, although they are not consistently labeled as such in his reports (some are only labeled, for example, "Opinion No. 1," while others are labeled, for example, "General Opinion No. 1"). For ease of reference, they will be referred to as "General Opinion 1" and "General Opinion 2" or an abbreviated form of either.

informed consent" because the IFUs did not inform of what Dr. Walmsley claims are safer alternative nonmesh procedures. *See, e.g.*, Exs. B, C, D, E, Walmsley Reports, Gen. Op. 2.

These opinions should be excluded. He provides no reliable bases for his insufficiency opinions. Nor is there any legal duty for an IFU to contain the information he claims it should and therefore his should-have-informed-of-alternative-procedure opinions are contrary to law.

ARGUMENTS AND AUTHORITIES

Ethicon and Johnson & Johnson incorporate by reference the standard for *Daubert* motions articulated by this Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

I. Dr. Walmsley's opinions that the IFUs are insufficient and prevented informed consent are unreliable and should be excluded.

In General Opinion 1, Dr. Walmsley addresses the sufficiency of the IFU for the TVT products to enable informed consent to be given to the patient. Dr. Walmsley will testify that these IFUs do not mention various mesh risks, including contraction, dyspareunia, mesh shrinkage, scar-plate formation, or difficulty removing the mesh if needed, which he claims makes informed consent impossible. *See* Exs. B, C, D, E, F, Walmsley Reports, Gen. Op. 1; *see also* Ex. L, Walmsley 6/6/16 (Martin) Dep. Tr. 22:3-12. This Court has twice rejected on reliability grounds these kind of insufficiency/informed-consent opinions. In both *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 542-43 (S.D.W. Va. 2014) and *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *34 (S.D.W. Va. 2014), Dr. Pence sought to offer the same opinions about the IFUs at issue in those cases as Dr. Walmsley seeks to offer here— namely, that deficiencies in IFUs prevented "true informed consent."

Like Dr. Pence in *Tyree* and *Sanchez*, Dr. Walmsley here provides no reliable basis showing that the unreferenced complications should have been included in the IFU. Although

Dr. Walmsley generically references in his reports a list of medical literature he purportedly relied upon in formulating his opinions, most of those references simply evaluate procedures that were available at the time of their publication, in addition to their efficacy. For example, the article by S. Abbott, *et al.—Evaluation and management of complication from synthetic mesh after pelvic reconstructive surgery: a multicenter study*—is precisely what the title says: a look at complications that can occur after mesh surgery with no mention of appropriateness of instructions. *See* Ex. G, 210 AM. J. OBSTET. GYNECOL. 163.e1-8 (Feb. 2014). Similarly, the article authored by A. Clave, *et al.—Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants*—is also exactly that: an evaluation of explants with no reference to what should be in the IFU. *See* Ex. H, 21 INT'L UROGYNECOL. J. 261-70 (2010). Like the authority relied by Dr. Pence in *Tyree* and *Sanchez*, this "authority" may demonstrate that complications occurred, but "it does not provide any guidance as to whether these complications should have been included as warnings" in the respective IFUs. *Tyree*, 54 F. Supp. 3d at 543; *Sanchez*, 2014 WL 4851989, at *35. Instead, all that remains is the expert's *ipse dixit*. *Tyree*, 54 F. Supp. 3d at 543; *Sanchez*, 2014 WL 4851989, at *35.

Dr. Walmsley's deposition testimony underscores the lack of authority for his insufficiency opinions. When asked the bases of the insufficiency opinion during his Wave 1 deposition, he did not even cite to the literature referenced in his reports. *Compare* Ex. I, Walmsley 3/23/16 (Fox) Dep. Tr. 42:17-43:2, *with* Exs. B, C, D, E, F, Walmsley Reports. Rather, he relied solely on his "clinical experience." Ex. I, Walmsley 3/23/16 (Fox) Dep. Tr. 42:17-43:2. As this Court said in *Carlson*, this is not enough. *Carlson v. Boston Scientific Corp.*, No. 2:13-CV-05475, 2015 WL 1931311, at *20 (S.D.W. Va. Apr. 28, 2015) (excluding expert's opinion based on unidentified sources, including "clinical experience," where expert failed to

explain how these sources "substantiate[d]" his opinion). And he has advanced no additional bases here—either in his reports or his latest depositions that should change the result here.

At bottom, Dr. Walmsley's insufficiency opinions fail for the same reason these same opinions failed in *Tyree* and *Sanchez*. They should be excluded in their entirety here.

Additionally, there is no legal requirement that an IFU contain a complete listing of all things that should be transmitted to the patient to obtain an informed consent. Indeed, Dr. Walmsley admitted surgeons gain knowledge of risks of stress urinary incontinence procedures through means other than an IFU—such as experience he gained during training, both in residency and fellowships (Ex. K, Walmsley 6/3/16 (Lindberg) Dep. Tr. 58:17-59:5), review of medical literature (*id*. at 59:23-60:3), practice guidelines from national organizations (*id*. at 60:11-17), and experience over the years (*id*. at 61:6-12). And he would expect other surgeons to have done the same. *Id*. at 62:3-8; *see also* Ex. J, Walmsley 6/6/16 (Bailey) Dep. Tr. 8:6-20; Ex. L, Walmsley 6/6/16 (Martin) Dep. 24:18-25:13; Ex. M, Walmsley 6/6/16 (Pridmore) Dep. Tr. 96:1-21.

The scope of a physician's communication about informed consent is measured by the patient's need for information that is material to the patient. *See, e.g.*, *Doe v. Planned Parenthood/Chicago Area*, 956 N.E.2d 564, 568-69 (Ill. App. Ct. 2011). There is no need for a physician to disclose "every conceivable risk which possibly could develop." *Taber v. Riordan*, 403 N.E.2d 1349, 1353 (Ill. App. Ct. 1980); *see also Whittington v. Mason*, 905 So. 2d 1261, 1264 (Miss. 2005); *Culbertson v. Mernitz*, 602 N.E.2d 98, 105-06 (Ind. 1992); *Pruette v. Ungarino*, 757 S.E.2d 199, 593 n.4 (Ga. App. Ct. 2014). The net result is that an opinion on informed consent must be related to specific facts in a specific case and should not be

circumscribed within the context of providing an opinion on general causation in a products liability case.[2]

II. Dr. Walmsley's opinion that the IFUs should have informed of alternative nonmesh procedures is contrary to law and should be excluded.

Courts consistently exclude expert testimony that is contrary to law because it is neither probative nor relevant, noting that this testimony cannot assist the jury in making factual determinations and also creates the potential for confusion. *See Martinez v. Porta*, 601 F. Supp. 2d 865, 866 (N.D. Tex. 2009) ("[A]n [expert's] opinion cannot be based on an erroneous legal premise."); *Whitney Nat'l Bank v. Air Ambulance by B & C Flight Mgmt., Inc.*, 516 F. Supp. 2d 802, 816 (S.D. Tex. 2007) (excluding experts' testimony that "assumes a legal duty that the record does not support"); *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-01928, 2010 WL 4259332, at *7 (S.D. Fla. Oct. 21, 2010) (excluding expert testimony because it "likely will be contrary to law"); *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, No. 1:08 GD 50000, 2010 WL 1796334, at *30-31 (N.D. Ohio May 4, 2010) (precluding expert witness from offering interpretation of federal regulations that contradicts a Supreme Court decision).

Despite this well-established rule of law, Dr. Walmsley seeks to testify that the IFUs here should have informed of allegedly "[s]afer alternative designs and procedures" that existed at the time. Exs. B, C, D, E, Walmsley Reports, Gen. Op. 2. According to Dr. Walmsley, these "safer

[2] The case of *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990), also illustrates this point. The court there confirmed that a physician has a duty to disclose information "material to the patient's decision." *Id*. at 483. Of course, that may vary from case to case. Indeed, the Supreme Court of California later noted: "Rather than mandate the disclosure of specific information as a matter of law, the better rule is to instruct the jury that a physician is under a legal duty to disclose to the patient all material information—that is, 'information which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject a recommended medical procedure'—needed to make an informed decision regarding a proposed treatment." *Arato v. Avedon*, 858 P.2d 598, 607 (Cal. 1993).

alternatives"—*i.e.*, autologous fascial slings—should have been included in the IFUs and without that information, the plaintiff "was unable to receive proper informed consent . . . ." Exs. B, C, D, E, Walmsley Reports, Gen. Op. 2. Yet Dr. Walmsley conceded in deposition that it was not his opinion that the IFU needed to specifically mention the autologous sling. Ex. K, Walmsley 6/3/16 (Lindberg) Dep. Tr. 16:14-19.[3]

Even so, Dr. Walmsley's should-have-informed-of-alternative-procedures opinions is contrary to law for two reasons. First, it assumes a duty that does not exist. There is no duty for a medical-device manufacturer to set forth in its IFU alternatives to the product that are allegedly safer, nor is there any duty for a physician to advise of alternative surgical techniques. There is no case in any jurisdiction establishing such a duty. Instead, the duty of a pharmaceutical manufacturer generally is to warn the prescribing physician of this risk of its products—not provide a diatribe of alternative products and procedures. Thereafter, the "prescribing physician can take into account the propensities of the [product], as well as the susceptibilities of his patient." *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974). The prescribing physician, in turn, warns the potential user. *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1280 (11th Cir. 2002) (applying Georgia law); *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 354 (Ill. 1996) (applying Illinois law); *West v. Searle & Co.*, 806 S.W.2d 608, 613-14 (Ark. 1991) (applying Arkansas law); *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 549 (Ind. Ct. App. 1979) (applying Indiana law); *Koehler v. Wyeth Labs. Div. of Am. Home Prods. Corp.*, No. NA 85-284-C, 1987 WL 47831, at *4-5 (S.D. Ind. Sept. 8, 1987); *see also* MISS. CODE ANN. § 11-1-63(c)(ii) (codifying learned-intermediary doctrine).

[3] Dr. Walmsley made the same concession in *Fox v. Ethicon, Inc.*, No. 2:12-cv-0878 (MDL General Dkt. 2171 at 5), and *Ridgley v. Ethicon, Inc.*, No. 2:12-cv-0311 (Dkt. 79 at 5), where plaintiffs advanced the same opinion but then effectively withdrew it in their *Daubert* responses.

Nor is there any duty that requires a manufacturer to compare one treatment to another. *Pluto v. Searle Labs.*, 690 N.E.2d 619, 621 (Ill. App. Ct. 1997) (finding that the manufacturer "had no duty to warn patients or physicians of the relative effectiveness of the Cu-7 as compared to other forms of birth control"); *see also Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th Cir. 1990) (holding that a manufacturer "is obligated to make a reasonable disclosure of all risks inherent in its own [product]"; it "is not obligated to provide a comparison of its [product] with others"); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 153-54 (Tex. 2012) ("Generally, a manufacturer is required to provide an adequate warning . . . of any potential harm that may result from the use of its product."); *see also id.* at 166-67 (noting that the duty to warn patients of "possible alternatives to any prescribed course of action rests with the prescribing physician"). Recognizing a duty to propose alternative therapies would turn each IFU into a long surgical manual requiring discussion of multiple surgeries and treatment options. On the contrary, the duty of a medical-device manufacturer is to set forth the risks of *its* product—not provide a diatribe of alternative products and procedures.

Dr. Walmsley's should-have-informed-of-alternative-procedures opinions are also contrary to law because information that must be included in a medical-device IFU is circumscribed by the FDA. *See* 21 C.F.R. § 801.109 (calling for information on use, "including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects" of which prescribers should be aware). The regulation does not require a description of alternate procedures. This regulation interacts with and is an exception to 21 U.S.C. § 352(f)(1) providing a prescription device is misbranded unless its labeling bears "adequate directions for use." *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1349 (10th Cir. 2015) (Lucero, J., dissenting); *Ellis*, 311 F.3d at 1284-85. An expert witness

should not be permitted to offer testimony about a proposed IFU change where it is inconceivable that the FDA would have permitted it.

Ethicon acknowledges that this Court in *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 713-15 (S.D.W. Va. 2014), found Dr. Walmsley's opinions on nonmesh alternatives sufficiently reliable when offered in the context of determining whether the mesh device at issue in that case was suitable for treating pelvic organ prolapse. His safer-alternative opinions here, however, are not offered in that context. Instead, they are offered for the purpose of challenging the adequacy of the IFUs for the TVT products. *Eghnayem* therefore provides no authority for permitting Dr. Walmsley's safer-alternatives opinions offered here. His proposed opinions here are not only contrary to law, but without any basis other than *ipse dixit*.

CONCLUSION

For the foregoing reasons, Dr. Walmsley's general-causation opinions—General Opinions No. 1 and 2 in these cases—should be excluded in their entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on July 21, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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